

Safety Data Sheet

SECTION 1: Identification

Contact information

General



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Product identifier	Avacincaptad Pegol
Synonyms	Avacincaptad Pegol Sodium, X01B, ARC1905, Zimura®
Trade name	Izervay™
Chemical family	PEGylated oligonucleotide
Recommended uses and restrictions	Pharmaceutical research, manufacture of clinical drug product, and clinical use.
Note	This SDS is written to address potential worker health and safety issues associated with the handling of the active pharmaceutical ingredient. The pharmacological, toxicological, and ecological properties of this substance have not been fully characterized. This SDS will be updated as more data become available.

SECTION 2: Hazard(s) identification

Classification of the substance or mixture	Not classified
Label elements	
GHS Hazard pictograms	Not applicable
GHS Signal word	Not applicable
GHS Hazard statements	Not applicable
GHS Precautionary statements	Not applicable
Other hazards	Avacincaptad pegol is a PEGylated single strand RNA aptamer that is a specific inhibitor of the complement system, a key pathway in initiating an inflammatory and immune response. Adverse effects (e.g., eye discomfort) were associated with intravitreal injection of the drug product. Systemic effects on complement pathways are not expected following avacincaptad pegol exposure.
Note	This substance does not meet criteria for classification under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA). Nevertheless, it should be handled with caution as it has not yet been fully tested and is pharmacologically active.

SECTION 3: Composition/Information on ingredients

Ingredient	CAS number	EINECS/ELINCS#	Amount	GHS classification
Avacincaptad Pegol (Main constituent)	1491144-00-3	N/A	≈ 100 %	Not classified

Note Full text of classification categories and H statements: see section 16

SECTION 4: First-aid measures

Description of first aid measures

Immediate medical attention and special treatment, if necessary	No.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Skin contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Eye contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Ingestion	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Most Important Symptoms/Effects	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.
Expected Symptoms/Effects, Acute and Delayed	See Sections 2 and 11

SECTION 5: Fire-fighting measures

Suitable (and unsuitable) extinguishing media	
Suitable extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the chemical	
Fire hazard	No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen and other fluorine-, and phosphorous-containing compounds.
Explosion hazard	No information identified. High concentrations of finely divided organic particles can explode if ignited.
Special protective equipment and precautions for fire-fighters	
Firefighting instructions	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures	
Protective equipment	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
Emergency procedures	Do not breathe dust.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	
Methods for cleaning up	DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations (see section 13). Decontaminate the area twice with an appropriate solvent (see section 9).
Other information	Dispose of materials or solid residues at an authorized site.
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7: Handling and storage

Precautions for safe handling	Follow recommendations for handling pharmaceutical agents (i.e. use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Do not breathe dust.
Conditions for safe storage, including any incompatibilities	
Storage conditions	Store in a closed container.
Storage temperature	-20 ± 5 °C
Specific end use(s)	Pharmaceuticals.

SECTION 8: Exposure controls/personal protection

Control parameters/Occupational Exposure Limits

Name	Issuer	Value
Avacincaptad Pegol	No data available	No data available

Appropriate engineering controls	Control exposures to below the OEL (for the active ingredient(s) if available). Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. If handling bulk powder: No open handling; control systems such as ventilated enclosures are required. Use of clean-in-place systems is recommended.
Respiratory protection	Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls.
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Eye protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin and body protection	Wear disposable coveralls appropriate to the task, booties, and safety glasses with side shields. Ensure gloves are protective against solvents in use. Protective garments (coveralls, disposable coveralls, lab coats) are not to be worn in common areas (e.g., cafeterias) or out-of-doors. Employees must be trained in proper gowning and degowning practices.
Other protective measures	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).
Environmental exposure controls	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

SECTION 9: Physical and chemical properties

Physical state	Solid
Appearance	Lyophilized powder / cake
Formula	PEGylated Fluoro-modified oligonucleotide
Molecular mass	Proprietary
Color	White to off-white, white to yellow
Odor	No data available
pH	No data available
Melting point	No data available
Freezing point	No data available
Boiling point	No data available
Flash point	No data available
Relative evaporation rate (butyl acetate=1)	No data available
Flammability (solid, gas)	No data available
Vapor pressure	No data available
Relative vapor density at 20 °C	No data available
Relative density	No data available
Solubility	No data available
Log Kow	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Fundamental burning velocity	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	No data available
Explosion limits	No data available
Explosive properties	No data available
Oxidizing properties	No data available

SECTION 10: Stability and reactivity

Reactivity	The product is non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	No dangerous reactions known under normal conditions of use.
Conditions to avoid	(See section 7: Handling and Storage).
Incompatible materials	No data available
Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Likely routes of exposure As a large molecular weight compound, it is not likely to be systemically absorbed through inhalation, skin contact, or ingestion.

Toxicological information**Acute toxicity****Component****Type****Dose**

Avacincaptad Pegol	No data available	No data available
Serious eye damage/irritation	No data available	
Skin corrosion/irritation	No data available	
Sensitization	No data available	
STOT-single exposure	Rat, IV LOAEL: 260 mg/kg Effects: Hematological changes, serum chemistry changes, lymphoid atrophy, thymic necrosis, bone marrow hypocellularity. Mortality at ≥ 540 mg/kg	
STOT-repeated exposure	Monkey, IV LOAEL: 86.2 mg/kg Effects: Mild hematological and serum chemistry changes. Rat (7-day), IV LOAEL: 367 mg/kg Effects: Lowered body weight; mild hematological and serum chemistry changes Monkey, IV LOAEL: 141 mg/kg Effects: Hematological and serum chemistry changes, changes to coagulation profile parameters, macrophage vacuolization (liver, spleen, lymph nodes, bone marrow, kidney, lungs, choroid plexus, adrenal gland). Mortality at 1410 mg/kg.	
Reproductive toxicity	No data available	
Developmental toxicity	No data available	
Genotoxicity	<i>In vitro</i> : Bacterial reverse mutation assay (e.g. Ames test): negative Chromosomal aberration assay (peripheral human lymphocytes): negative <i>In vivo</i> : Mouse micronucleus assay: negative	
Carcinogenicity	No data available	
Aspiration hazard	No data available	
Experience with humans	See "Section 2 - Other Hazards".	

SECTION 12: Ecological information

Toxicity**Component****Type****Concentration**

Avacincaptad Pegol	No data available	No data available
Persistence and degradability	No data available	
Bioaccumulative potential	No data available	
Mobility in soil	No data available	
Results of PBT assessment	No data available	
Other adverse effects	No data available	
Note	No special precautions are needed..	

SECTION 13: Disposal considerations

Waste treatment methods Used product should be disposed of according to local, state, and federal regulations. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g. appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g. appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14: Transport information

Transport Based on the available data, this substance is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

UN number None assigned.

UN proper shipping name None assigned.

Transport hazard class(es) (DOT) None assigned.

Packing group None assigned.

Marine pollutant	Based on the available data, this substance is not regulated as an environmental hazard or a marine pollutant.
Special transport precautions	No special precautions required.
Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
Chemical safety assessment	No chemical safety assessment has been carried out
TSCA	Drugs are exempt from TSCA.
SARA Section 313 - Emission Reporting	This substance or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.
California Proposition 65	California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm
Additional information	No additional information available

SECTION 16: Other information

Data sources	Information from published literature and internal company data.
Abbreviations and acronyms	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System
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Disclaimer	The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.